REMARKS

Claims 8-9, 14-5, 20-23, 30 and 31-34 are pending and rejected. Claims 1-5, 10-13, 18-19 and 24-29 have been cancelled without prejudice. Applicants reserve the right to prosecute subject matter of the canceled claims in subsequent patent applications.

New claim 31 has been added to recite the transgenic plant according to claim 20, wherein said bacterium is *Thermomonospora.* Support is in the specification on page 10, lines 6-7.

New claim 32 has been added to recite the transgenic plant according to claim 20, wherein wherein the endoglucanase is thermostable. Support for this amendment is in the specification on page 4, line 6.

New claim 33 has been added to recite a transgenic seed obtained from the plant of claim 20. Support is in the specification on page 7, lines 9-10.

New claim 34 has been added to recite a transgenic seed obtained from the plant of claim 20, wherein said seed comprises said nucleic acid. Support is in the specification on page 7.

No new matter has been added by this amendment.

Claim Rejections under 35 USC 112, second paragraph

Claim 30 would have been rejected under 35 USC 112, second paragraph, as allegedly lacking anticedent basis for "the microbial source". Claim 30 has been amended to recite "microorganism".

Claim Rejection under 35 USC 112, first paragraph

Claims 6-9, 14, 16-17, 19-23 and 30 are rejected under 35 USC 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed.

Applicants respectfully disagree with this rejection.

The legal standard for meeting the written description requirement under section 112, first paragraph, is whether "the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 1563-64, 19 USPQ2d 1111,1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

The patent application need not teach what is already known to those of ordinary skill in the art (*Hyatt v. Boone*, 146 F.3d 1348, 47 USPQ2d 1128(Fed. Cir. 1998) citing *In re Eltgroth*, 419 F.2d 918, 921, 164 USPQ 221, 223 (CCPA 1970).

Applicants respectfully disagrees with a statement in the Office Action on page 4 where it states: "the specification only teaches one nucleic acid encoding a fungal ß-1,4-endoglucanases, and nucleic acid encoding a fungal ß-1,4-endoglucanases from only one *Thermomonospora* species" (emphasis added). The specification specifically describes three endoglucanases from the bacteria, *Thermomonospora fusca*, E1, E2 and E5 on page 14 of the specification. Further, the references cited on page 15 describe additional endoglucanases (cellulases) from bacterial and fungal sources that were available to those of ordinary skill in the art at the time of the filing of this application.

The specification as filed provides references describing several bacterial and fungal endoglucanases known to those in the art at the time the application was filed. These endoglucanases were available to those in the art. In particular, on pages 14-15 there list several sources of "cellulase genes for transformation into plants". The specification lists the *T. fusca* E1, E2 and E5 genes in particular set forth in references (GeneBank Accession No. L20094, Jung et al.1993), GenBank Accession no. M73321, Ghangas et al., 1988; Lao et al., 1991; and GenBank Accession No. L01577; Collmer and Wilson, 1983; Lao et al. 1991, respectively. The specification continues and states, "other cellulase genes may be transformed into plants according to the present invention as well, including all of the cellulase genes disclosed in the following references: Collmer *et al.* (1983) Bio/Technology 1:594-601; Ghanges *et al.* (1988) Appl. Environ. Microbiol. 54:2521-2526; Wilson (1992) Crit. Rev. Biotechnol. 12:45-63; Jung *et al.*

(1993) Appl. Environ. Microbiol. 59:3032-3043; Lao et al. (1991) J. Bacteriol. 173:3397-3407; and Thomas *et al.*, "Initial Approaches to Artificial Cellulase Systems for Conversion of Biomass to Ethanol"; Enzymatic Degradation of Insoluble Carbohydrates, J.N. Saddler and M.H. Penner, eds., ACS Symposium Series 618:208-36, 1995, American Chemical Society, Washington, D.C. These include, but are not limited to, endoglucanases, exoglucanases, and ß-D-glucosidases derived from microorganisms such as bacteria and fungi."

In particular, Wilson (1992, Crit. Rev. Biotechnology 12:45-63) on page 46, col. 1, describes two cellulase genes isolated from *Thermomonospora curvata* (subsequently reclassified as *T. fusca*); five different cellulase genes from *Microbispora bispora* (citing Waldron *et al.*) and one cellulase from the fungus *Streptomyces* and one cellulase from the *Micromonospora*. Within this reference on page 56, col. 2, the authors compare the recently cloned cellulases with previously discovered cellulases from the bacteria *Pseudomonas fluorescens*, *Cellulomonas fimi* endoglucanase and *Bacillus* cellulase.

Lao *et al.*, (1991) J. Bacteriol. 173:3397-3407 describes three endoglucanase genes from *T. fusci* (E2, E5 and N-terminal of E4).

Thomas *et al.*, (1995) ACS Symposium Series 618:208-236 describes cellulases isolated from a variety of sources such as the fungus, *Trichoderma reesei* and the bacteria *Acidothermus cellulolyticus* and *Thermotoga meapolitana* (page 209, 3rd paragraph). Further, on page 210, the article states: "more than 60 cellulolytic fungi have been reported . . . representing the soft-rot, brown-rot, and white-rot fungi" (citations omitted). Also a review of the literature found 46 unique bacterial producers of cellulases including the genera *Thermomonospora, Microbispora, Acidothermus, Pseudomonas, Therotoga, Erwinia*, and *Acetivibrio*.

Additionally, various genetic databases, such as Genebank, were available at the time of the filing of this patent application that listed known endoglucanase sequences. For example, endoglucanase genes were isolated and identified in the three fungi *Humicola insolens* (Genbank Accession no. X76046; published in Mol. Gen. Genet. (1994) 243:253-260); *Penicillium janthinellum* (Genbank Accession no. X89564; published in Curr. Genet. (1996) 29:490-495); and *Hypocrea jecorina* (Genbank

Accession no. Z33381; published in Mol. Microbial. (1994) 13:219-228) (copies attached as Exhibits 1-3).

Given all these references and sources of endoglucanases from fungi or bacteria, one of ordinary skill in the art would be able to identify other sources of fungal and bacterial cellulases/endoglucanases beyond those of *T. fusci* used specifically in the examples of this application. It is not necessary in a patent application to describe information and facts known to those skilled in the art nor list every possible endoglucanase known at the time of the invention. The application as filed provides sufficient written description to identify other endoglucanases from bacteria and fungi to those of ordinary skill in the art.

Applicants submit these remarks and amendments overcome this rejection and request its withdrawal.

Claim Rejection under 35 USC 112, first paragraph

Claims 6-9, 14, 16-17, 19-23 and 30 are rejected under 35 USC 112, first paragraph, as allegedly not enabled by the specification for all ß-1,4-endoglucanases. The specification is considered enabled for *T. fusca* ß-1,4-endoglucanase.

Applicants respectfully disagree with this rejection.

Enablement of a disclosure "is not precluded by the necessity for some experimentation such as routine screening." In re Wands, 858 F.2d 731, 736-7 (Fed. Cir. 1988) (citations omitted). The experimentation necessary must not be undue. Id. At 737. Undue experimentation is experimentation that would require a level of ingenuity beyond what is expected from one of ordinary skill in the field. Fields v. Conover, 170 USPQ 276, 279 (CCPA 1971). The factors that can be considered in determining whether an amount of experimentation is undue have been listed in Wands, 858 F.2d at 737. Among these factors are: the amount of effort involved, the guidance provided by the specification, the presence of working examples, the amount of pertinent literature and the level of skill in the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. Id.

The relevant inquiry for determining whether the scope of the claims is commensurate with the specification is "whether the scope of enablement provided to one of ordinary skill in the art by the disclosure is such as to be commensurate with the scope of protection sought by the claims." In re Moore, 439 F.2d 1232, 1236 (CCPA 1971) (emphasis added). "A patent need not teach, and preferably omits, what is well known in the art." Hybridtech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), cet. Denied, 480 U.S. 947 (1987).

While predictability of the art can be considered in determining whether an amount of experimentation is undue, mere unpredictability of the result of the experiment is not a consideration. Indeed, the Court of Customs and Patent Appeals has specifically cautioned that the unpredictability of the result of an experiment is not a basis to conclude that the amount of experimentation is undue (see In re Angstadt, 190 USPQ 214 (CCPA 1976)).

Enablement doesn't require detailed description of every possible embodiment.

There is no requirement in section 112, first paragraph, that the specification provide a detailed description of every possible embodiment covered by the claims. The Examiner is respectfully referred to the controlling opinion in In re Goffe, 191 USPQ 429, 431 (1976), which makes clear that a claim may cover embodiments not actually reduced to practice prior to the filing date of the application:

> For all practical purposes, the Board would limit appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute. However, to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specific for "preferred" materials in a process . . . would not serve the constitutional purpose of promoting progress in the useful arts.

The claimed method calls for integration into plant cells of a DNA construct encoding a ß-1,4-endoglucanase. The regulatory regions instruct the plant cell to

transcribe the region of the DNA coding for the endoglucanase. The critical aspect of the method is not the nature of the endoglucanase, but rather the use of appropriate regulatory sequences which would function in the host plant cells to express the coding sequence. By using appropriate regulatory sequences, endoglucanases can be produced in plants cells as exemplified by the production of *T. fusca* endoglucanase.

In line with the holding in Goffe, supra, it does not serve the constitutional purpose of promoting progress in the useful arts if others may take Applicants' example of production of the *T. fusca* endoglucanase in a plant cell and substitute the coding sequence from a structural gene for another endoglucanase to obtain expression of that endoglucanase. The Examiner is fully aware that substituting one structural gene for another in an expression cassette is within the knowledge of one of ordinary skill in the art and does not require "undue experimentation."

As admitted by the Examiner in the Advisory Action, "plant promoters are described in the literature within the full scope of the claims".

Many bacterial and fungal endoglucanases are described in the reference cited in the specification. The specification also describes how to make expression cassettes and express an exemplary endoglucanase in the plastid of plant cells. Given the descriptions in the specification, one of ordinary skill in the art would be able to substitute an endoglucanase of *T. fusci* and replace it with another endoglucanase from a different fungal or bacterial source without any undue experimentation.

The presently claimed invention is NOT to the endoglucanase genes themselves, but to plants transgenically modified to express microbial endoglucanases. Therefore, one need only describe samples of endoglucanases to enable those of skill in the art to produce the invention.

Applicants submit these remarks and amendments overcome this rejection and request its withdrawal.

CONCLUSION

Applicants point out that the above remarks and amendments overcome the rejections. Reconsideration of the application and allowance of all pending claims is earnestly solicited.

Should the Examiner wish to discuss any of the above in greater detail or deem that further amendments should be made to improve the form of the claims, the Examiner is invited to telephone the undersigned at the Examiner's convenience.

Respectfully submitted,

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Telephone: 919-765-5071

Syngenta Biotechnology, Inc.
3054 E. Cornwallis Road
Research Triangle Park, NC 27709-2257

Date: April 24, 2006

Exhibit 1


```
LOCUS       HICMC3                  1239 bp    DNA     linear   PLN 18-APR-2005
DEFINITION  H.insolens CMC3 mRNA for endoglucanase.
ACCESSION   X76046
VERSION     X76046.1  GI:505194
KEYWORDS    CMC3 gene; endoglucanase.
SOURCE      Humicola insolens
  ORGANISM  Humicola insolens
            Eukaryota; Fungi; Ascomycota; mitosporic Ascomycota; Humicola.
REFERENCE   1  (bases 1 to 1239)
  AUTHORS   Dalboege,H. and Hansen,H.P.H.
  TITLE     A novel method for efficient expression cloning of fungal enzyme
            genes
  JOURNAL   Mol. Gen. Genet. 243 (3), 253-260 (1994)
   PUBMED   8190078
REFERENCE   2  (bases 1 to 1239)
  AUTHORS   Dalboege,H.
  TITLE     Direct Submission
  JOURNAL   Submitted (04-NOV-1993) H. Dalboege, Manager GeneExpress, Novo
            Nordisk A/S, Symbion, Fruebjergvej 3, 2100 Copenhagen OE, DENMARK
FEATURES             Location/Qualifiers
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                     /db_xref="taxon:34413"
     gene            16..1182
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                     /EC_number="3.2.1.4"
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//
```

Exhibit 2


```
LOCUS       PJEGL2                  1373 bp    mRNA    linear   PLN 13-SEP-1996
DEFINITION  P.janthinellum mRNA for endoglucanase2.
ACCESSION   X89564
VERSION     X89564.1  GI:984165
KEYWORDS    egl2 gene; endo-1,4-beta-glucanase; endoglucanase 2.
SOURCE      Penicillium janthinellum
  ORGANISM  Penicillium janthinellum
            Eukaryota; Fungi; Ascomycota; Pezizomycotina; Eurotiomycetes;
            Eurotiales; Trichocomaceae; mitosporic Trichocomaceae; Penicillium.
REFERENCE   1  (bases 1 to 1373)
  AUTHORS   Mernitz,G., Koch,A., Henrissat,B. and Schulz,G.
  TITLE     Endoglucanase II (EGII) of Penicillium janthinellum: cDNA sequence,
            heterologous expression and promotor analysis
  JOURNAL   Curr. Genet. 29 (5), 490-495 (1996)
   PUBMED   8625430
REFERENCE   2
  AUTHORS   Mernitz,G., Koch,A., Henrissat,B. and Schulz,G.
  TITLE     EndoglucanaseII of Penicillium janthinellum-sequence, heterologous
            expression and promoter analysis
  JOURNAL   Unpublished
REFERENCE   3  (bases 1 to 1373)
  AUTHORS   Mernitz,G.
  TITLE     Direct Submission
  JOURNAL   Submitted (12-JUL-1995) G. Mernitz, Institut fuer Mikrobiologie,
            Max-Reimann-Strasse 16, D 14532 Kleinmachnow, FRG
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                     /codon_start=1
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/

Jan 30 2006 12:09:03

Exhibit 3

1: Z33381. Reports T.reesei (QM9414)...[gi:485863]

- Features
- Sequence

```
LOCUS       TRGE14BG                1124 bp    DNA     linear   PLN 26-JUN-1995
DEFINITION  T.reesei (QM9414) gene for endo-1,4-beta-glucanase.
ACCESSION   Z33381
VERSION     Z33381.1  GI:485863
KEYWORDS    endo-1,4-beta-glucanase; endo-1,4-beta-glucanase V.
SOURCE      Hypocrea jecorina
  ORGANISM  Hypocrea jecorina
            Eukaryota; Fungi; Ascomycota; Pezizomycotina; Sordariomycetes;
            Hypocreomycetidae; Hypocreales; Hypocreaceae; Hypocrea.
REFERENCE   1  (bases 1 to 1124)
  AUTHORS   Saloheimo,A., Henrissat,B., Hoffren,A.M., Teleman,O. and
            Penttila,M.
  TITLE     A novel, small endoglucanase gene, egl5, from Trichoderma reesei
            isolated by expression in yeast
  JOURNAL   Mol. Microbiol. 13 (2), 219-228 (1994)
   PUBMED   7984103
REFERENCE   2  (bases 1 to 1124)
  AUTHORS   Saloheimo,A.
  TITLE     Direct Submission
  JOURNAL   Submitted (05-MAY-1994) Saloheimo A., VTT Biotechnology and Food
            Research, Espoo, Finland
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                     /product="endo-1,4-beta-glucanase V (EGV)"
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                     and beta-glucan"
                     /note="Based on hydrophobic cluster analysis, EGV belongs
```

```
                     to family K of cellulases/xylanases and family 45 of
                     glycosyl hydrolases together with EGB of Pseudomonas
                     fluorescens and EGV of Humicola insolens."
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                     /number=1
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     exon            205..270
                     /gene="egl5"
                     /number=2
     intron          271..332
                     /gene="egl5"
                     /number=2
     exon            333..923
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